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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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In re Application of)
)
SCHRÖDER) Art Unit: 1652
)
Serial No. 09/622,419) Examiner: Saidha, Tekchand
)
Filed: August 16, 2000)
)
For: PROCESS FOR PREPARING BIOTIN

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents, PO Box 1450, Alexandria, VA 22313-1450, on: December 2, 2003
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December 2, 2003
Date of Signature

Honorable Comm'r. of Patents
PO Box 1450
Alexandria, VA 22313-1450

PETITION TO THE COMMISSIONER UNDER 37 CFR §1.144

Sir:

Applicants hereby petition to the Honorable Commissioner to review the final restriction requirement set forward in the office action dated May 14, 2003.

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STATEMENT OF MATERIAL FACTS

1. This application is a US national stage application filed in the US on August 16, 2000 based on international application PCT/EP 99/01052, which was filed on February 17, 1999.

2. In the first office action dated February 12, 2003 the examiner identified seven claim groupings, three of which contain claims 1-6 & 12 (I-III), three of which contain claims 7-11 & 14 (IV-VI) and one which contains claim 13 only. The differences between each of Groups I-III and IV-VI lie in the specifically identified gene sequences. Groups I and IV identify SEQ ID NOs 1 and 3, Groups II and V identify SEQ ID NOs 1 and 5, and Groups III and VI identify SEQ ID NOs 1 and 7.

3. Applicants filed a timely response to the restriction requirement on March 12, 2003. Applicants elected Group I as defined by the examiner, with traverse, and provided reasons for the traversal in the response.

4. In a first office action on the merits, dated May 14, 2003, the examiner maintained the restriction requirement and made it final.

5. Applicants filed a timely response to the office action on August 6, 2003, responding to the issues on the merits in which claim 12 was canceled and new claim 15 was presented.

6. In a final office action dated October 7, 2003, the examiner refused to consider newly presented claim 15, based on the earlier unity of invention finding, and reaffirmed the restriction requirement.

7. Applicants have filed an amendment under 37 CFR §1.116 in response to the issues on the merits maintained in the examiner's final action, which is of even date with the present petition to the commissioner.

8. Applicants have not yet filed a notice of appeal under 37 CFR §1.191 in this application.

STATUS OF THE CLAIMS

The claims pending in this application are claims 1-11 and 13-15. A copy of the pending claims as amended in applicants' amendment under 37 CFR §1.116 is found in the attached appendix.

REMARKS

The present claims are drawn to subject matter which shows unity of invention and which under current US and PCT practice should be examined concurrently. PCT Rule 13 and 37 CFR §1.475 state that a national stage application may "relate to a group of inventions so linked as to form a single inventive concept." This "requirement of unity of invention" is met where there exists "a technical relationship among those inventions involving one or more of the same or corresponding special technical features" (*id.*).

The present examiner has identified seven special technical features in the present claims, each associated with a different defined group. The special technical

features of groups I-III are identified as specific combinations of SEQ ID NOs 1, 3, 5, and 7 "used in transforming a host," and the special technical features of groups IV-VI are identified to be "gene construct[s] using" specific combinations of SEQ ID NOs 1, 3, 5, and 7 (office action of February 12, 2003, p.3). The specifically identified combinations of these sequences are SEQ ID NOs 1 & 3 (groups I and IV), SEQ ID NOs 1 & 5 (groups II and V), and SEQ ID NOs 1 & 7 (groups III and VI). The examiner argues that each special technical feature in a given group is one "which [the other] Groups ... do not share," and "[t]hus the various groups ... show a lack of unity of invention" (*id.*).

As indicated above, unity of invention requires that there be a "technical relationship ... involving one or more of the same or corresponding special technical features" (PCT Rule 13, 37 CFR §1.475). The gene constructs of groups IV-VI are produced using specific combinations of SEQ ID NOs 1, 3, 5, & 7, and the transformations of groups I-III, again, use these same specific combinations of SEQ ID NOs 1, 3, 5, & 7. In order to successfully transform a host organism, it is necessary to produce a construct of the subject genes. Accordingly, there is a technical relationship between a gene construct containing specific genes and transformation of a host organism with those genes. Thus, unity of invention exists between groups I and IV, groups II and V, and groups III and VI as identified by the examiner and based on the special technical features identified by the examiner.

Further, the genes represented by SEQ ID NOs 3, 5, & 7, bioS1-bioS3, are each

biotin synthesis genes, and serve corresponding roles in each of the examiner's defined groups. The combination of SEQ ID NO 1 with each of these other genes individually is also a special technical feature of the present claims. This special technical feature is present in each of groups I-VI, and thus unity of invention is present among them.

Group VII contains claim 13 only, which is drawn to a process for using the gene depicted in SEQ ID NO 7, alone or together with one or more biotin synthesis genes. The improved biotin synthesis achieved by this process is a special technical feature shared with the claims in groups I-VI. Accordingly, the unity of invention requirement is fulfilled with respect to this group also.

CONCLUSION

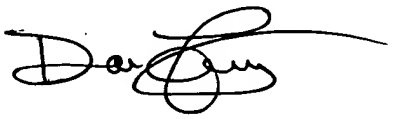
In view of the foregoing remarks, it is urged that applicants's claims meet the unity of invention requirement as set forth in PCT Rule 13 and 37 CFR §1.475 which is applicable in the present case under PCT Article 27. It is therefore requested that the examiner's restriction requirement be traversed, that the finality of the office action dated October 7, 2003 be withdrawn and that the application be returned to the examiner for further examination. It is also respectfully solicited that any unfairness in the compensation of the examiner due to differences between US national restriction practice under 35 USC §121 and unity of invention provisions under the PCT be resolved internally at the USPTO.

A check in the amount of $130.00 is attached to cover the required fee for

this petition.

Please charge any shortage in fees due in connection with the filing of this paper, including Extension of Time fees to Deposit Account No. 11-0345. Please credit any excess fees to such deposit account.

Respectfully submitted,
KEIL & WEINKAUF



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APPENDIX - PRESENT CLAIMS AS AMENDED UNDER 37 CFR §1.116

1. A process for producing biotin wherein an S-adenosylmethionine synthase gene, having the sequence SEQ ID No. 1, and at least one further biotin biosynthesis gene bioS1, bioS2 or bioS3, having the sequences SEQ ID No. 3, SEQ ID No. 5 or SEQ ID No. 7, or functional variants, analogues or derivatives thereof having from 80 to 100% homology based on the corresponding amino acid sequence and possessing the corresponding SAM synthase, bioS1, bioS2, or bioS3 enzymic activity, are expressed in a prokaryotic or eukaryotic host organism which is able to synthesize biotin, this organism is cultured and the synthesized biotin is used directly after separating off the biomass or after purifying the biotin.

2. (canceled)

3. A process as claimed in claim 1, wherein an organism selected from the group of the genera Escherichia, Citrobacter, Serratia, Klebsiella, Salmonella, Pseudomonas, Comamonas, Acinetobacter, Azotobacter, Chromobacterium, Bacillus, Clostridium, Arthrobacter, Corynebacterium, Brevibacterium, Lactococcus, Lactobacillus, Streptomyces, Rhizobium, Agrobacterium, Staphylococcus, Rhodotorula, Sporobolomyces, Yarrowia, Schizosaccharomyces or Saccharomyces is used as the host organism.

4. A process as claimed in claim 1, wherein a regulation-defective biotin mutant is used as the host organism.

5. A process as claimed in claim 1, wherein at least one copy of the genes having the sequences SEQ ID No.1, SEQ ID No. 3, SEQ ID No. 5 and SEQ ID No. 7 as claimed in claim 1 is expressed in a prokaryotic or eukaryotic host organism either alone or together with one or more copies of at least one further biotin gene selected from the group bioA, bioB, bioF, bioC, bioD, bioH, bioP, bioW, bioX, bioY or bioR.

6. A process as claimed in claim 1, wherein at least one copy of the genes having the sequences SEQ ID No.1, SEQ ID No. 3, SEQ ID No. 5 and SEQ ID No. 7 as claimed in claim 1 is expressed in a prokaryotic or eukaryotic host organism either alone or, on a shared vector or on separate vectors, together with one or more copies at least one further biotin gene selected from the group bioA, bioB, bioF, bioC, bioD, bioH, bioP, bioW, bioX, bioY or bioR.

7. A gene construct which comprises an S-adenosylmethionine synthase gene, having the sequence SEQ ID No. 1, and at least one further biotin biosynthesis

gene bioS1, bioS2 or bioS3, having the sequences SEQ ID No. 3, SEQ ID No. 5 and SEQ ID No. 7, or their functional variants, analogues or derivatives, which have from 80 to 100% homology based on the corresponding amino acid sequence and possess the corresponding SAM synthase, bioS1, bioS2, or bioS3 enzymic activity, and which is functionally linked to one or more regulatory signals for the purpose of increasing gene expression and/or protein expression and/or whose natural regulation has been switched off.

8. A gene construct as claimed in claim 7, which has been inserted into a vector which is suitable for expressing the gene in a prokaryotic or eukaryotic host organism.

9. A gene construct as claimed in claim 7, wherein the genes having the sequences SEQ ID No. 1, SEQ ID No. 3, SEQ ID No. 5 and SEQ ID No. 7, and also their functional variants, analogues or derivatives, are present in several copies in the gene construct.

10. A gene construct as claimed in claim 7, wherein the S-adenosylmethionine synthase gene, SEQ ID No. 1, and at least one further biotin biosynthesis gene bioS1, bioS2 or bioS3, having the sequences SEQ ID No. 3, SEQ ID No. 5 and SEQ ID No. 7, and also their functional variants, analogues or derivatives, as claimed in claim 7, are present in the gene construct or vector together with one or more copies of at least one further gene selected from the group bioA, bioB, bioF, bioC, bioD, bioH, bioP, bioW, bioX, bioY or bioR.

11. An organism which comprises a gene construct as claimed in claim 7.

12. (canceled)

13. The use of the bioS3 gene, having the sequence SEQ ID No. 7, or of its functional variants, analogues or derivatives, either alone or in combination with at least one further gene selected from the group S-adenosylmethionine synthase gene, bioS1, bioS2, bioA, bioB, bioF, bioC, bioD, bioH, bioP, bioW, bioX, bioY or bioR, for producing biotin.

14. The use of a gene construct as claimed in claim 7 for producing biotin.

15. A process for producing biotin wherein an S-adenosylmethionine synthase gene having the sequence SEQ ID No. 1, and at least one biotin biosynthesis gene selected from the group consisting of O-acetylserine sufohydrolase A, O-acetylserine sulfohydrolase B, β-cystathionase, nifS, and their prokaryotic and

eukaryotic homologues, are expressed in a prokaryotic or eukaryotic host organism which is able to synthesize biotin, this organism is cultured and the synthesized biotin is used directly after separating off the biomass or after purifying the biotin.